

**REMARKS**

In the Office Action mailed August 20, 2003, the Examiner rejected claims 18, 31-33, 38-41, and 49-51 under 35 U.S.C. § 112, second paragraph. Claims 23, 24 and 26 stand rejected under 35 U.S.C. § 102(b). Claims 4 and 55 are allowed.

With entry of this Amendment, claims 4, 9-16, 18, 23-28, 31-33, 42-48, and 52-55 are pending in this application. Claims 38-41 and 49-51 are canceled without disclaimer of or prejudice to the subject matter recited therein. Claims 4, 9, 18, 23, 31-33, and 55 are amended. Claims 9 and 55 are amended to correct the lack of antecedent basis for the word "region." Claim 4 is amended to depend from claim 55 instead of claim 57. Support for the amendment to claim 23 can be found, for example, in paragraph 12, pages 6-7, of the as-filed specification. No new matter is added by these amendments.

Applicants submit payment in the amount of \$258.00, for three independent claims added since the original filing of this continuation-in-part application.

**I. Formal Matters**

**A.** According to the Examiner, the numbering of the claims in the previous Amendment (filed June 17, 2003) is not in accordance with 37 C.F.R. § 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. The Examiner informs Applicants that the original application was filed with claims 1-54, and the claim added in the previous amendment should have been numbered 55 instead of 57. (Office Action mailed August 20, 2003, page 2.)

Applicants thank the Examiner for correcting the numbering of the added claim to 55.

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**B.** The Examiner maintains that a claim for priority under 35 U.S.C. § 119(a)-(d) cannot be based on application FR 95 02117. (*Id.*)

Applicants acknowledge the Examiner's position that they are not entitled to the benefit of the filing date of French Patent Application FR 95 02117. Applicants continue to disagree with the Examiner's position for the reasons of record and request that this issue be held in abeyance until such time as they choose to rely on the filing date of FR 95 02117.

**II. The Claims Are Definite**

The Examiner rejects claims 18, 31-33, 38-41, and 49-51 under 35 U.S.C. § 112, second paragraph, alleging that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (Office Action mailed August 20, 2003, page 2.)

According to the Examiner, there is insufficient antecedent basis for the limitation "[T]he plasmid according to claim 17" of claim 18 because claim 17 has been canceled. (*Id.*, page 3.)

Applicants have amended claim 18 to independent form. Therefore, the rejection of claim 18 is moot.

According to the Examiner, there is insufficient antecedent basis for the limitation "[T]he cultured recombinant cell according to Claim 30" in claims 31-33 because claim 30 has been canceled. (*Id.*)

Applicants have amended claims 31-33 to independent form. Therefore, the rejection of claims 31-33 is moot.

According to the Examiner, there is insufficient antecedent basis for the limitation "[T]he method according to Claim 37" in claim 38 because claim 37 has been canceled. (*Id.*)

Applicants have canceled claim 38 without disclaimer of or prejudice to the subject matter contained therein. Therefore, the rejection of claim 38 is moot.

According to the Examiner, there is insufficient antecedent basis for the limitation "[T]he method according to Claim 34" in claim 49 because claim 34 has been canceled. The rejection also applies to claims 50 and 51, which also depend from canceled claim 34 (through claim 49). (*Id.*)

Applicants have canceled claims 49-51 without disclaimer of or prejudice to the subject matter contained therein. Therefore, the rejection of claims 49-51 is moot.

For the reasons above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 18, 31-33, 38-41, and 49-51 under 35 U.S.C. § 112, second paragraph.

### **III. The Claims Are Not Anticipated**

The Examiner maintains the rejection of claims 23 and 24 under 35 U.S.C. § 102(b) as allegedly being anticipated by Black (Gene 46: 97-101, 1986) for the reasons of record set forth in the previous Office Action (Office Action mailed August 20, 2003, page 3.) In addition, the Examiner maintains the rejection of claims 23, 24, and 26 under 35 U.S.C. § 102(b) as allegedly being anticipated by Peredelchuk *et al.* (Gene

In the previous Office Action, the Examiner asserted that Black discloses a plasmid comprising attR and attL sequences flanking an expression cassette, wherein the expression cassette is the tetracycline or ampicillin resistance gene in "one part of the cointegrate" or any of the  $\lambda$  genes of "the other part of the cointegrate." (Office Action mailed December 17, 2002, page 6.) In addition, the Examiner asserted that Peredelchuk discloses plasmids comprising an expression cassette, specifically one for chloramphenicol acetyltransferase (*cat*), positioned between  $\lambda$  attR and attL sequences. (*Id.*, page 7.)

In response, Applicants argued that the instant claims recite a plasmid comprising an expression cassette positioned between attL and attR, and a plasmid with a selection marker gene that is outside the expression cassette. (Amendment filed June 17, 2003, page 8.) Applicants argued that the application makes it clear that an "expression cassette" contains "a gene of interest under the control of a transcription promoter and a transcription terminator active in a mammalian cell." (*Id.*, pages 8-9.) Because Peredelchuk's plasmids are intended for use only in bacteria, the *cat* gene, which is a selectable marker, is not "under the control of a transcription promoter and a transcription terminator active in a mammalian cell" as required by the instant claims. (*Id.*, page 10).

In response to Applicants' earlier arguments, the Examiner asserts that "the features upon which applicant relies (i.e., transcription promoter and terminator active in mammalian cells) are not recited in the rejected claim(s)." (Office Action, page 4.) The Examiner also asserts that "the claims recite merely 'expression cassette' without

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limiting its contents, and the claims do not exclude antibiotic resistance from the expression cassette.” (*Id.*) Moreover, the Examiner asserts that,

with respect to claim 24, any of the lambda genes meet the limitation of being the expression cassette, which is separated by attR and attL from the ori and antibiotic resistance. The limitation “outside the expression cassette”, does not exclude embodiments where the attR and attL flank the expression cassette and the ori or selection marker gene. This limitation only excludes the selection marker gene from being expressed from the expression cassette. In the case of Peredelchuk, one antibiotic resistance gene meets the limitation of selection marker and the other meets the limitation of expression cassette.

*Id.*

Without acquiescing in the arguments set forth by the Examiner, Applicants have amended claim 23 to include the limitation “wherein said expression cassette lacks a gene for a selectable marker and comprises a gene of interest under control of a transcription promoter and a transcription terminator active in a mammalian cell.” Support for the amendment may be found in the as-filed specification. Applicants respectfully assert that this limitation obviates the rejection of claims 23, 24, and 26. At a minimum, neither the promoter nor the terminator in Black’s plasmid would be expected to be active in mammalian cells.<sup>1</sup> Similarly, Peredelchuk’s *cat* gene is not

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<sup>1</sup> In fact, Black actually describes “ $\lambda$  DNA containing a pBR322 derivative flanked by the  $\lambda$  attL and attR sites” that can “be specifically recircularized by excisive  $\lambda$  recombination to yield the pBR322 derivative.” Black, Abstract. In Black, it is the pBR322 that is equivalent to the instant invention’s expression cassette. However, regardless of whether a pBR322-derived gene or, as the Examiner asserts, a  $\lambda$  gene is the “gene of interest” in Black, none of those genes is “under control of a transcription promoter and

under control of a transcription promoter and a transcription terminator active in a mammalian cell.<sup>2</sup>

For the reasons above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 24, and 26 under 35 U.S.C. § 102(b).

#### **IV. The Double Patenting Rejections**

The Examiner maintains the rejection of claims 9-11, 14-16, 23, 24, 26-28, 42-44, and 48, and rejects claim 52 under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-18, 24, 25, and 28-37 of U.S. Patent No. 6,143,530, in view of Backman (EP 0160571), for the reasons of record set forth in the previous Office Action. (*Id.*, page 5) In addition, the Examiner maintains the rejection of claims 42-46 under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 34 and 37 of U.S. Patent No. 6,143,530 and Backman (EP 0160571) as applied to claims 42-45, and in further view of Bigger *et al.* (J. Biol. Chem. 276 (25):23018-23027, 22 June 2001) for the reasons of record set forth in the previous Office Action. (*Id.*)

Solely to expedite prosecution, and without acquiescing in the rejection, Applicants have enclosed a Terminal Disclaimer that disclaims any term beyond the expiration date of U.S. Patent No. 6,143,530. Accordingly, Applicants respectfully

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<sup>2</sup> Without providing any justification, the Examiner asserts that because Peredelchuk's plasmid comprises both a gene for chloramphenicol resistance (i.e., *cat*) and a gene for tetracycline resistance (i.e., *tet*), the *tet* gene is a selectable marker, but the *cat* gene is a gene of interest. Certainly, those skilled in the art recognize that a plasmid may contain more than one gene for a selectable marker (e.g., pBR322, which comprises genes for both ampicillin and tetracycline resistance).

request withdrawal of the obviousness-type double patenting rejection of claims 9-11, 14-16, 23, 24, 26-28, 42-46, 48, and 52.

**V. Responses to Objections**

The Examiner objects to claims 12, 13, 25, 47, 53, and 54 because they depend on rejected base claims. The Examiner indicates that the claims would be allowable if rewritten in independent form including all the limitations of the respective base claims and any intervening claims.

Applicants respectfully submit that the Terminal Disclaimer filed herewith renders these objections moot.

**V. Conclusion**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims are definite. Moreover, this claimed invention is not anticipated in view of the prior art references cited by the Examiner. Applicants therefore request the reconsideration and reexamination of the application, and the timely allowance of the pending claims. Should the Examiner feel that this application is not in condition for allowance, Applicants request that he contact their undersigned representative at 202-408-4185.

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If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 18, 2003

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